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Clinical Effect of Poly Herbal Unani Formulation on Dyslipidemia- A Randomized Trial

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ABSTRACT

Background: In adults aged 30-70 with primary and moderate hyperlipidemia, the present study took place to investigate the therapeutic benefits of a polyherbal unani preparation called Garlitab. *Methods***:** It was a prospective open label, herbal coded test drug-controlled, randomized trial. Out of total screened patients we were enrolled 212 hyperlipidemic patients of 30–70 years in the study fulfilling the inclusion criteria, we were recruited them from OPD of a hospital in Munshiganj and different Unani clinics of Dhaka, Bangladesh after obtaining written informed consent from the patients. Selected individuals were allocated into two groups at random. Group1 Received 500 mg Garlitab tablets twice daily and Group 2 received tablet atorvastatin calcium 10 mg 2 times daily. Height, weight, and blood pressure were recorded along with blood samples. The random distributions were carried out by a research assistant utilizing a random numbers table. Blood samples were taken at the beginning of the trial, 1.5 months later, and 3 months following the intervention. *Results:* Results for the test medication revealed a substantial drop in cholesterol levels between baseline and the data collected after three months and in case of male it was from 241.72±38.11 to 218.24±34.06 mg/dL for total cholesterol, from 198.27±30.57 to 173.54±29.34 mg/dL for LDL and from 280.78±85.81 to 207.07±51.40 mg/dL for triglyceride. HDL increases from 33.05±3.21 to 34.69±3.13 mg/dL in male patients. The control drug atorvastatin calcium also showed a significant decrease in lipids between baseline and after 3 months data and in case of male it was from 241.92±31.54 to 174.90±22.87 mg/dL for total cholesterol, from 196.20±30.91 to 130.30±24.29 mg/dL for LDL and from 279.48±115.35 to 141.27±59.55 mg/dL for triglyceride. It increases HDL from 32.00±2.25 to 34.03±2.19 mg/dL in male patients. Between the baseline and the 3-month data, the test medicine for females significantly reduced total cholesterol, LDL, and triglycerides and it was from 244.64±52.18 to 220.12±45.07 mg/dL, from 200.32±30.57 to 173.54±29.34 mg/dL and from 272.32±99.69 to 195.25±60.68 mg/dL respectively. HDL increases from 33.77±3.36 to 35.03±3.23 mg/dL. Between the baseline and the 3-month data, the control medication for females significantly reduced total cholesterol, LDL, and triglycerides and it was from 247.74±37.95 to 175.26±29.54 mg/dL, from 197.65±27.89 to 130.91±22.04 mg/dL and from 271.57±94.52 to 142.00±50.88 mg/dL respectively. It increases HDL from 32.22±2.32 to 33.46±2.94 mg/dL. *Conclusions:* According to the results of the study, the polyherbal formulation Garlitab can lower cholesterol levels. It may be a useful medication for treating primary hyperlipidemia.

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Introduction

Dyslipidaemias involve modifications to the plasma lipid profile that often correspond to clinical disorders. Nevertheless, some kinds of dyslipidaemia, such as hypertriglyceridaemia, are linked to serious disorders in other organ systems, such as non-alcoholic fatty liver disease and acute pancreatic inflammation. Dyslipidaemias, Major risk factors for heart attack and stroke involve excessive plasma LDL-C (Low-Density Lipoprotein) holesterol amounts in particular. Dyslipidaemias can develop as a result of secondary conditions, with the second category occurring more frequently, such as diabetes mellitus, obesity, or an unhealthy lifestyle. As a result of primary or familial dyslipidaemias, genes may also be to blame. In 1990, increased plasma LDL-C (Low-Density Lipoprotein) holesterol ranked as the 15th most important risk factor for death. By 2007 and 2019, it has risen to the 11th and 8th positions, respectively. Because of the condition's elevated risk of heart attacks and strokes, it is the most common form of dyslipidaemia (Pirillo et al., 2021). Dyslipidaemia, a name used to refer to variations in lipids, comprises high levels of triglycerides (TG), low levels of HDL-C (High-

Density Lipoprotein), a rise in levels of LDL-C (Low-Density Lipoprotein), and elevated amounts of total cholesterol (TC) (Mohamed-Yassin et al., 2021). One of the known risk factors for cardiovascular disease is dyslipidemia. (Mohamed-Yassin et al., 2021). Comprehensive evaluations reveal a substantial relationship between high LDL-C (Low-Density Lipoprotein) and atherosclerotic cardiovascular disease (Cardiovascular Disease (CVD)) (Legrand et al. 2013; Collins et al., 2016). Additionally linked to Cardiovascular Disease (CVD) was low HDL-C (High-Density Lipoprotein) (Di Angelantonioet al., 2009). The development of atherosclerosis and Cardiovascular Disease (CVD) has been associated with high TC and LDL-C (Low-Density Lipoprotein), although more recent research has cast doubt on this relationship (Stückle, 2015; Ravnskov et al., 2018).

The impact of boosting HDL-C (High-Density Lipoprotein) in preventing Cardiovascular Disease (CVD) has also been questioned, even though some studies have shown that non-HDL-C (High-Density Lipoprotein) predicts CV risk better than LDL-C (Low-Density Lipoprotein) (Robinson et al., 2009; Arsenault et al., 2009).

In comparison to Europe (53.7%) and America (47.7%), South East Asia (30.3%) and Africa (23.1%) had much lower prevalence rates of hypercholesterolaemia in adults. (Mohamed-Yassin et al., 2021). The prevalence rates reported by Lin et al., (Lin et al., 2016) Nevertheless, ranged widely throughout the Asia-Pacific countries, from 9% in Indonesia to 46.9% in the Philippines. High TG, low HDL-C (High-Density Lipoprotein), and high LDL-C (Low-Density Lipoprotein) are more common, with prevalence rates ranging from 7.8% to 47.2%, 13.9% to 38.6%, and 10.1% to 71.3%, respectively (Lin et al., 2016). In Noubiap et al.'s 2018 comprehensive analysis of dyslipidemia in Africa, the prevalence of increased TC, high LDL-C (Low-Density Lipoprotein), elevated TG, and low HDL-C (High-Density Lipoprotein) was reported to be 25.5%, 28.6%, 17%, and 37.4%, respectively (Noubiap et al., 2015).

Due to rising urbanization, socioeconomic growth, longer life expectancies, insufficient nutrition, and alterations in lifestyle, the population of Southeast Asia is currently at an increased risk of Cardiovascular Disease (CVD) (Choudhury et al., 2014). One of the developing countries in Southeast Asia, Bangladesh, has seen an increase in the incidence of non-communicable diseases and accompanying mortality during the previous several decades (Saquib et al., 2012). A recent examination of the literature found that adult Bangladeshis living in urban regions are more likely to have Cardiovascular Disease (CVD) than those residing in remote regions (Chowdhury et al., 2018). Several studies support this (Islam et al., 2012; Mithal et al., 2014; Joshi et al., 2014), In Bangladesh and other South Asian nations, dyslipidemia—a modifiable risk factor for Cardiovascular Disease (CVD)—is on the rise.

Our study drug Garlitab is a polyherbal Unani composition made of six priceless herbs, including Garlic *(Allium sativum)* dry extract, Onion *(Allium cepa)* dry extract, Black plum *(Syzygium cumini)* seed dry extract, Mango *(Mangifera* indica) leaf dry extract, Nutmeg (Myristica fragrans) fruit dry extract, Clove (Syzygium aromaticum) flower dry extract. It is designed to treat hyperlipidemia, particularly by reducing the LDL-C (Low-Density Lipoprotein) level of blood.

Clove (Syzygium aromaticum)

The spice name clove refers to the tiny, dried flower buds of Eugenia caryophyllata, also known as *Syzygium aromaticum*, which are reddish brown in color (Habtemariam et al., 2019).). Figure 1, 2 and 3 is the picture of: Dried cloves, Clove tree flower buds and the compound eugenol is responsible for most of the characteristic aroma of cloves.

Figure 1. Dried cloves. (Source- Internet)

Figure 2. Clove tree flower buds. (Source- Internet)

Clove (Syzygium aromaticum) is being used to treat dyslipidaemias for long time. According to one clinical study published in 2017, Clove supplementation resulted in statistically significant increases in HDL cholesterol and the highest reductions in total cholesterol, triglycerides, LDL, and VLDL cholesterol in the hyperlipidemic group (Balasasirekha et al., 2012).

Garlic (Allium sativum)

Garlic (Allium sativum) is a kind of bulbous plant with flowers that belonging to the Allium genus. Amongst its nearest cousins are the onion, shallot, leek, and chive (Block et al., 2010). Numerous civilizations, especially Egypt, Japan, China, Rome, and Greece, utilized garlic as a traditional alternative (Garlic, 2022). Figure 4, 5 and 6 is the picture of: Raw Garlic, Garlic Plants and Alliin Garlic contains the sulfur-containing substance

Garlic is traditionally used for hyperlipidemic patients. A parallel-designed randomized controlled clinical study included 112 hyperlipidemic individuals between the ages of 30 and 60. After receiving garlic and lemon juice, those with hyperlipidemia showed improvements in the level of blood pressure, fibrinogen levels, and cholesterol (Aslani et al., 2016).

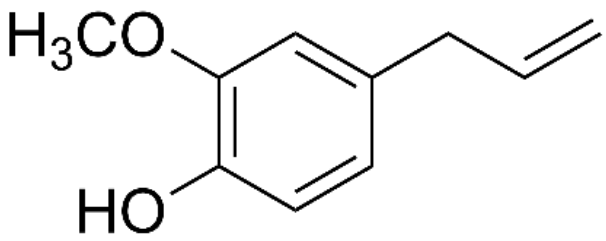

Figure 3. The compound eugenol is responsible for most of the characteristic aroma of cloves. (Source- Internet)

Figure 4. Raw Garlic. (Source- Internet)

Figure 5. Garlic Plants. (Source- Internet)

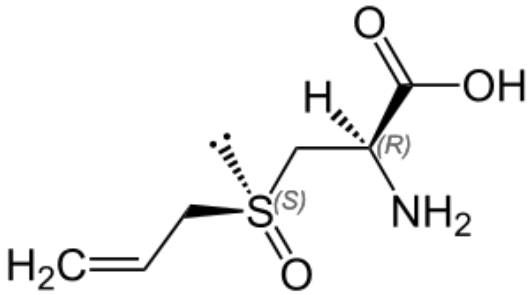

Figure 6. Garlic contains the sulfur-containing substance alliin. (Source- Internet)

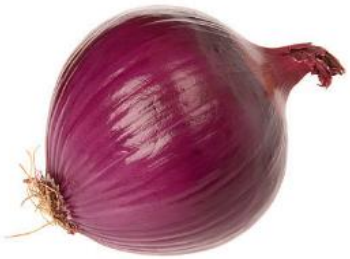

Figure 7. Raw Onion. (Source- Internet)

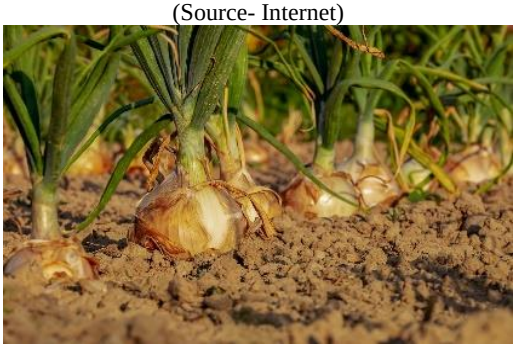

Figure 8. Onion Plants. (Source- Internet)

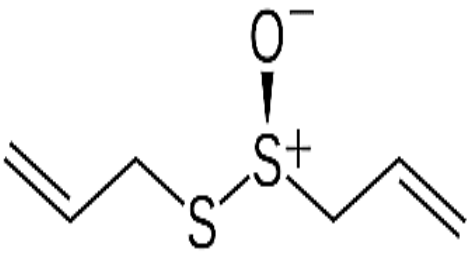

Figure 9. Onion contains the sulfur-containing substance allicin. (Source- Internet)

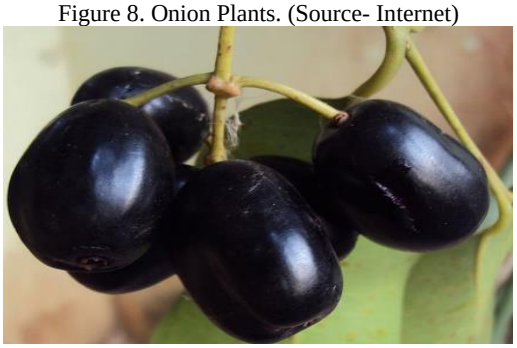

Figure 10. Raw Black plum. (Source- Internet)

Figure 11. Black plum Seed. (Source- Internet)

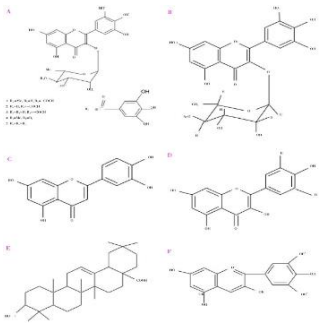

Figure 12. (1) Mearnsetin, Myricetin, (2), Myricetin-3-O-(400-O-acetyl)-a-L-rhamnopyranoside (3), Myricet Gentiobiose, (Source- Internet)

Onion (Allium cepa)

The most commonly farmed a member of the genus Allium is the onion (Allium cepa L., from the Latin cepa, meaning "onion"). It is additionally frequently referred to as the bulb onion or the common onion (Khoury et al., 2013). Numerous health advantages, including a decrease in LDL cholesterol, blood pressure reduction, have been linked to allicin found in studies (Medicalnewstoday.com, 2022). Figure 7, 8 and 9 is the picture of: Raw Onion, Onion Plants and Allicin Onion contains the sulfur-containing substance

Black plum (Syzygium cumini)

Known for its berries, timber, and ornamental value, Syzygium cumini is an evergreen tropical tree in the Myrtaceae flowering plant family. Additionally, it goes by the names jamun, jaman, jambul, jambon, Malabar plum, Java plum, black plum, etcetera. Figure-10, 11 and 12 is the picture of: Raw Black plum, Black plum Seed and (1) Mearnsetin, Myricetin, (2), Myricetin-3-O-(400-O-acetyl)-a-L-rhamnopyranoside (3), Myricet Gentiobiose.

The jambolan has a long history in complementary medicine, and all the components of the plant can be used medicinally (Reynertson et al., 2005). Syzygium cumini seed powder administration substantially decreased white adipose tissue (WAT) weights, blood sugar, serum insulin and plasma lipids including total cholesterol, triglyceride, LDL, and HDL content (Sharma et al., 2017).

Mango (Mangifera indica) leaf

For thousands of years, the leaves of a certain type of mango, *Mangifera indica*, have been utilized in traditional Chinese medicine, Unani medicine, and the medicine of Ayurveda (Batool et al., 2018). Figure-13, 14 and 15 is the picture of: Raw Mango leaf, Mango tree, Chemical make-up of a few phytochemicals present in mango fruit and plants.

Mangifera indica leaf extract, which is high in phytosterols, is a great source of a nutraceutical element that may decrease blood cholesterol levels. Substantial cholesterol-lowering effects were shown in rats given a methanol extract of M. indica leaves at a dose of 90 mg/kg body weight, and a dose of 5000 mg/kg rat body was also demonstrated to be harmless (Gururaja, 2017).

Figure 13. Raw Mango leaf. (Source- Internet)

Figure 14. Mango tree. (Source- Internet)

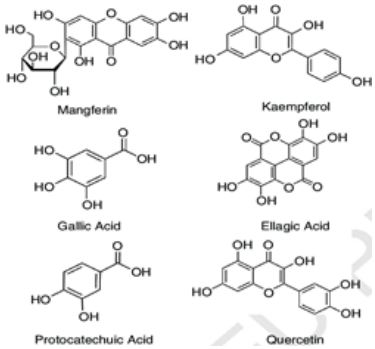

Figure 15. Chemical make-up of a few phytochemicals present in mango fruit and plants (Kabir, Y et al.,2017).

Figure 16. Dried Nutmeg. (Source- Internet)

Figure 17. Nutmeg tree. (Source- Internet)

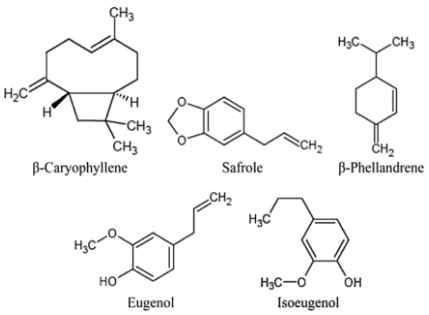

Figure 18. The chemical make-up of several significant nutmeg seed oil elements includes caryophyllene, safrole, phenanthrene, eugenol, and isoeugenol (Gupta E, 2020).

Nutmeg (Myristica fragrans)

An evergreen tree with dark-green leaves known as the fragrant nutmeg or real paprika (M. fragrans) is planted for two spices that are prepared from its fruit. The seed from several Myristica tree species, or the ground spice made from that seed, is known as nutmeg (FAO, 2018). Figure-16, 17 and 18 is the picture of: Dried Nutmeg, Nutmeg tree and the chemical make-up of several significant nutmeg seed oil elements includes caryophyllene, safrole, phenanthrene, eugenol, and isoeugenol.

Methods

Type of study

With a 1:3 allocation ratio to the intervention and herbal-coded test drug groups, this study was a prospectively open-label, herbal-coded test drug-controlled, randomized analysis.

Study population

The study included participants of both sexes with abnormal lipid profiles who were 30 to 70 years old and receiving therapy for primary hyperlipidemia.

Sample size

Random sampling was used to choose and register patients. Following screening tests such a fasting lipid profile, an average of 2–3 responders were registered each clinic day. The clinical trial had 212 participants in total. After satisfying both the inclusion and exclusion requirements, the test and positive control groups each included 3:1 patients (test n=159, positive control n=53). Figure 19 is the RCT Flow Diagram.

Sampling technique

Subjects were randomly assigned to receive either the herbal product or the intervention. Each supplement has a code correlating to the trade name box. Participants and the researcher in charge of participant recruitment, data collection, and analysis (MM) were aware of the supplements each participant received.

Inclusion criteria

Both male and female participants is included if they-give their consent to participate the study, Age 30–70 years, a fasting LDL cholesterol reading that is higher than159 mg/dL.

Exclusion criteria

Any gastrointestinal conditions that could interfere with the intestinal activities and absorption of the polyphenols were grounds for exclusion from the study; was taking any drugs that might have affected outcomes, such as those for controlling blood pressure, blood sugar, or cholesterol; was using additional natural health supplements, such as fish oil or phytosterols, which are known to affect cholesterol or polyphenols; a significant health condition (such as liver/thyroid problems or a recent major surgery); are nursing or pregnant; smoked cigarettes or had a cardiac defibrillator installed. If a participant had a history of, or is now experiencing, depression, anxiety, or indicators of cognitive deterioration, they were disqualified from the cognitive and mood tests.

Data collection

In addition to baseline biochemical measurements, fasting (>11 hours) venous blood samples were also collected at 1.5 and 3 months.

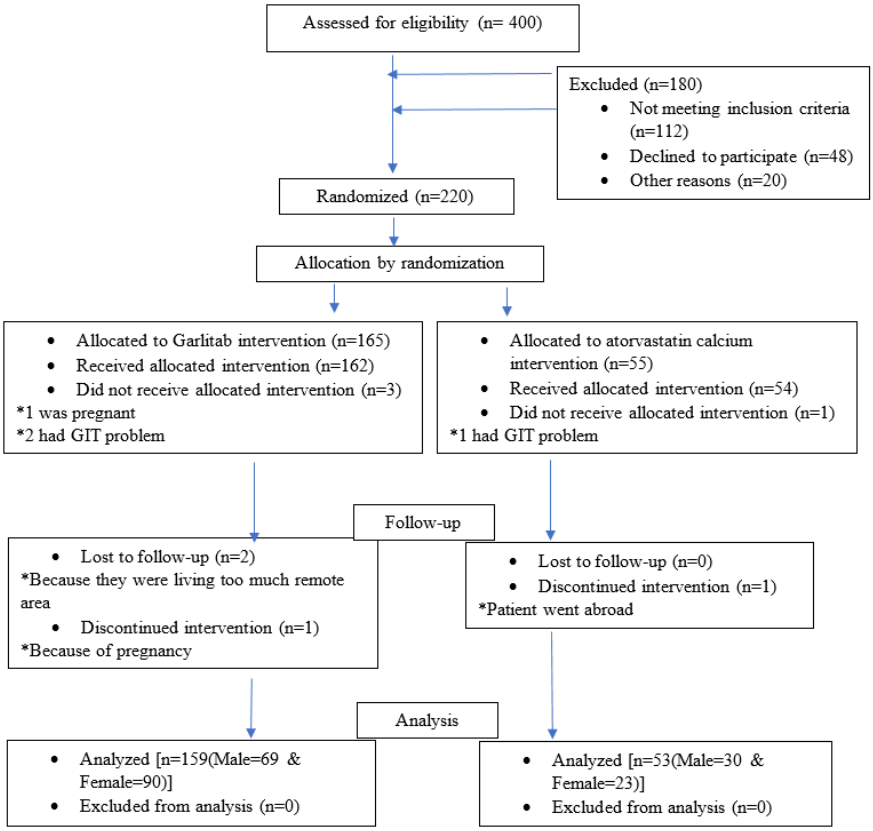

Figure 19. RCT Flow Diagram

Data analysis

Mean and standard deviation were calculated along with descriptive statistics. Cross tabulation and chi square statistics were used to identify associations between socio-demographic factors. SPSS (version 18, SPSS, Chicago, IL, USA) was used to analyze the data, and a two-sided P value of 0.05 was regarded as significant. Blood samples were taken at the start of the trial to create a baseline, after 1.5 months of intervention, and after 3 months of intervention in order to quantify parameters of metabolic profiles. To assess the effectiveness of baseline data and data after three months of lipids, a two-tail paired t-test was performed for the main effect study. Chi-square analysis for categorical data was used to analyze baseline general features. When we got a significant result in the two-tail paired t-test, we performed Tukey's post hoc comparisons to determine pairwise differences.

Results

Response on total cholesterol levels of test group

159 individuals received the test medication, 69 of them were men and 90 of whom were women (Table 1A, B). The baseline mean total cholesterol level for male responders was 241.72±38.11 mg/dL. According to Table 10, total cholesterol levels decreased after 6 weeks of medication treatment to 227.20±36.47 mg/dL and after 12 weeks to 218.24±34.06 mg/dL. For female responders, the mean total cholesterol level was 244.64±52.18 mg/dL at baseline. As indicated in table 11, total cholesterol levels decreased after 6 weeks of medication delivery to 228.24±48.10 mg/dL and after 12 weeks to 220.12±45.07 mg/dL.

Table 1(A). Age distribution by treatment group according to gender.

	Age group	Treatment group			
		Test group		Positive Control group	
		N	(%)	N	(%)
Male	≤35 years	15	21.7	11	36.7
	36-45 years	24	34.8	8	26.7
	46-55 years	17	24.6	6	20.0
	56-65 years	12	17.4	4	13.3
	>65 years	1	1.4	1	3.3
	Total	69	100.0	30	100.0
Female	≤35 years	22	24.4	6	26.1
	36-45 years	39	43.3	12	52.2
	46-55 years	19	21.1	3	13.0
	56-65 years	9	10.0	2	8.7
	>65 years	1	1.1	0.0	0.0
	Total	90	100.0	23	100.0

Table 1(B). Age distribution of the treatment group (Average).

Age group	Test group		Positive Control group	
	N	(%)	N	(%)
≤35 years	37	23.3	17	32.1
36-45 years	63	39.6	20	37.7
46-55 years	36	22.6	9	17.0
56-65 years	21	13.2	6	11.3
>65 years	2	1.3	1	1.9
Total	159	100.0	53	100.0

Table 2. Mean age and SD distribution of treatment group according to gender.

Treatment group	Sex	Mean	Number	Std. deviation
Positive control group	Male	44.07	30	11.350
	Female	41.91	23	8.570
	Total	43.13	53	10.202
Test group	Male	45.38	69	10.586
	Female	43.48	90	9.401
	Total	44.30	159	9.945
Total	Male	44.98	99	10.782
	Female	43.16	113	9.223
	Total	44.01	212	9.999

Table 3. Distribution of treatment group according to gender.

Sex	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Male	69	43.4	30	56.6
Female	90	56.6	23	43.4
Total	159	100.0	53	100.0

Table 4. Distribution of treatment group according to Occupation.

Occupation	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Unemployed	11	6.9	2	3.8
Service holder	42	26.4	21	39.6
Agricultural work	13	8.2	1	1.9
Business	11	6.9	6	11.3
Day laborer	3	1.9	-	-
House wife	72	45.3	17	32.1
Retired	7	4.4	6	11.3
Total	159	100.0	53	100.0

Table 5. Distribution of treatment group according to Diabetes.

Diabetes	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Type 1 DM	25	15.7	5	9.4
Type 2 DM	4	2.5	5	9.4
No diabetes	130	81.8	43	81.1
Total	159	100.0	53	100.0

Table 6. Distribution of treatment group according to treated hypertension

Treated HTN	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Yes	34	21.4	11	20.8
No	125	78.6	42	79.2
Total	159	100.0	53	100.0

Table 7. Distribution of treatment group according to smoking history

Smoking history	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Current smoker	42	26.4	22	41.5
Non smoker	117	73.6	31	58.5
Total	159	100.0	53	100.0

Table 8. Distribution of treatment group according to Body Mass Index

BMI classification (Asian)	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Under weight <18.5	-	-	-	-
Normal range 18.5-22.9	59	37.1	28	52.8
Over weight 23.0-27.5	97	61.0	25	47.2
Obese c ≥ 27.5	3	1.9	-	-
Total	159	100.0	53	100.0

Table 9(A). Distribution of treatment group according to 10-year AS CARDIOVASCULAR DISEASE (CVD) risk for patients at the time of enrollment

10-year As Cardiovascular Disease (CVD) risk for patients at the time of enrollment	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Low risk (<5%)	13	8.2	2	3.8
Borderline risk (5%-7.4%)	34	21.4	4	7.5
Intermediate risk (7.5%-19.9%)	67	42.1	8	15.1
High risk (more and equal 20%)	45	28.3	39	73.6
Total	159	100.0	53	100.0

Table 9 (B). Distribution of the treatment group according to their10 year ASCARDIOVASCULAR DISEASE (CVD) risk assessment after three months of enrollment.

10-year Ascardiovascular Disease (CVD) risk for patients after three months of enrollment	Treatment group			
	Test group		Positive control group	
	N	(%)	N	(%)
Low risk(<5%)	65	40.9	7	13.2
Borderline risk (5%-7.4%)	14	8.8	9	17.0
Intermediate risk (7.5%-19.9%)	65	40.9	23	43.4
High risk (more and equal 20%)	15	9.4	14	26.4
Total	159	100.0	53	100.0

Table 10. Distribution of treatment group according to lipid profile (Male)

Lab parameters	Treatment group		P–value
	Test group =69	Positive control group = 30	
Total cholesterol level(mg/dL)			
Baseline Data	241.72±38.11	241.92±31.54	
Data after 1.5-month	227.20±36.47	202.80±25.87	
Data after 3 months	218.24±34.06	174.90±22.87	0.000*
HDL (mg/dL)			
Baseline Data	33.05±3.21	32.00±2.25	
Data after 1.5-month	34.08±3.39	33.13±2.43	
Data after 3 months	34.69±3.13	34.03±2.19	0.000*
LDL (mg/dL)			
Baseline Data	198.27±30.57	196.20±30.91	
Data after 1.5-month	181.07±31.14	143.37±27.16	
Data after 3 months	173.54±29.34	130.30±24.29	0.000*
Triglyceride (mg/dL)			
Baseline Data	280.78±85.81	279.48±115.35	
Data after 1.5-month	230.65±65.60	234.20±66.64	
Data after 3 months	207.07±51.40	141.27±59.55	0.000*

* P–value < 0.05 = Significant

Table 11. Distribution of treatment group according to lipid profile (Female)

Lab parameters	Treatment group		P–value
	Test group =90	Positive control group =23	
Total cholesterol level(mg/dL)			
Baseline Data	244.64±52.18	247.74±37.95	
Data after 1.5-month	228.24±48.10	201.13±31.30	
Data after 3 months	220.12±45.07	175.26±29.54	0.000*
HDL (mg/dL)			
Baseline Data	33.77±3.36	32.22±2.32	
Data after 1.5-month	34.45±3.44	33.26±2.47	
Data after 3 months	35.03±3.23	33.46±2.94	0.000*
LDL (mg/dL)			
Baseline Data	200.32±30.57	197.65±27.89	
Data after 1.5-month	181.07±31.14	143.70±25.47	
Data after 3 months	173.54±29.34	130.91±22.04	0.000*
Triglyceride(mg/dL)			
Baseline Data	272.32±99.69	271.57±94.52	
Data after 1.5-month	210.92±74.24	161.04±53.43	
Data after 3 months	195.25±60.68	142.00±50.88	0.000*

* P–value < 0.05 = Significant

Table 2 indicates the Mean age and SD distribution of the treatment group according to gender in both the treatment and control groups. Table 3 shows the Distribution of the treatment group according to gender where 56.6% are men and 43.4% female. Table 4 shows the distribution of the treatment group according to Occupation, where Service holders 39.6% and Housewives 32.1% most of the numbers. Table 5 shows the distribution of the treatment group according to Diabetes where Type I DM and Type II DM are more prevalent respectively. Table 6 shows the distribution of treatment groups according to treated hypertension and found that most of the patients in both groups are not treated with hypertension 78.6% and 79.2% respectively in the test and control groups. Table 7 shows the distribution of treatment groups according to smoking history we found most of the participants are non-smokers 73.6% and 58.5% of both test and control groups. Table 8 ındicating the distribution of the treatment group according to Body Mass Index and we found that most of the population 61.0% in the Test group were overweight. Table 9(A) shows the distribution of the treatment group according to 10-year As Cardiovascular Disease (CVD) risk for patients at the time of enrollment, Table 9 (B) presents the Distribution of the treatment group according to their year As Cardiovascular Disease (CVD) risk assessment after three months of enrollment and we found most of the population is under Intermediate risk (7.5%-19.9%).

Response on HDL Cholesterol levels of test group

159 individuals received the test medication, 69 of them were men and 90 of whom were women. The baseline mean HDL level for male responders was 33.05±3.21 mg/dL. As demonstrated in Table 10, the HDL level increased after six weeks of medication treatment to 34.08±3.39 mg/dL and after twelve weeks to 34.69±3.13 mg/dL. The baseline mean HDL level for female responders was 33.77±3.36 mg/dL. As indicated in table 11, the HDL level rose to 34.45±3.44 mg/dL and 35.03±3.23 mg/dL after 6 weeks and 12 weeks of medication delivery.

Response of Test and Control drug in LDL Cholesterol levels

159 individuals received the test medication, 69 of them were men and 90 of whom were women. The baseline mean LDL level for male responders was 198.27±30.57 mg/dL. As demonstrated in table 10, the LDL level decreased after six weeks of medication treatment to 181.07±31.14 mg/dL and after twelve weeks to 173.54±29.34 mg/dL. The baseline mean LDL level for female responders was 200.32±30.57 mg/dL. As indicated in table 11, the LDL level decreased to 181.07±31.14 and 173.54±29.34 mg/dL after 6 weeks and 12 weeks of medication delivery.

Response of Test and Control drug in triglycerides levels

At baseline, the mean triglyceride level in 69 male patients receiving the test medication was 280.78±85.81 mg/dL, while the mean level in 30 male cases receiving the control medication was 279.48±115.35 mg/dL. As indicated in table 10, total triglyceride levels were decreased after 12-weeks of medication treatment to 207.07±51.40 mg/dL from the baseline in the test group and 141.27±59.55 mg/dL in the positive control group. At baseline, the mean triglycerides level in the test group of 90 female patients was 272.32±99.69 mg/dL, while the mean level in the positive control group of 23 female cases was 271.57±94.52 mg/dL. According to table 11, total triglyceride levels in the test group were lowered from baseline values to 195.25±60.68 mg/dL and to 142.00±50.88 mg/dL in the positive control group following the 12-week medication treatment.

Discussion

One research examines how garlic affects people with type 2 diabetes mellitus who have dyslipidemia, one of the main cardiovascular risk factors. The findings demonstrate that garlic significantly decreased total cholesterol (-28 mg/dl, -12.03% P= 0.001) and LDL-C (Low-Density Lipoprotein) (-30 mg/dl, - 17.99% P= 0.001), whereas the placebo-treated group (n=32) experienced a non-significant reduction in total cholesterol (-2 mg/dl, - 0.9% P= ns) and LDL-C (Low-Density Lipoprotein) (-3 mg/dl, - 1.6% P= n.s). Patients receiving garlic therapy had substantially higher HDL cholesterol (3.35 mg/dl, 8.81% P= 0.05) compared to the placebo group (0.62, 1.6% P= n.s.), but there was no discernible change in triglyceride levels between the two groups. The results show that, as compared to a placebo, garlic dramatically decreased blood total cholesterol and LDL cholesterol and somewhat increased HDL cholesterol (Ashraf et al., 2005). In another study, the impact of garlic powder at 5% and 10% concentrations on the plasma lipid profile in hypercholesterolemic rats was examined. In order to induce hypercholesterolemia, male albino rats were given a diet that included 20% fat and 1% cholesterol for two weeks. The treated groups' plasma total cholesterol and LDL-C (Low-Density Lipoprotein) levels were considerably lower than those of the hypercholesterolemic control group, according to the results- HDL-C (High-Density Lipoprotein), however, showed a substantial improvement ($P<0.05$) (Ajayi et al., 2014). This double-blind randomized, placebo-controlled intervention study was conducted in 46 hypercholesterolemic subjects who had failed or were noncompliant with drug therapy to assess the hypocholesterolemic effect of an enteric-coated garlic supplement standard for allicin-releasing potential in mild to moderate hypercholesterolemic patients. Each participant received dietary advice to reduce fat consumption, enteric-coated Australian garlic powder pills with a possible allicin release of 9.6 mg, or identical placebo tablets. After 12 weeks, it was shown that those who took garlic supplements significantly reduced their total cholesterol and LDL cholesterol, whereas those who took placebos saw no significant change in their TC, LDL-C (Low-Density Lipoprotein), or HDL levels (Kannar et al., 2001). The cardiovascular system's response to pure allicin was examined in the study. To achieve this, 20 naturally hypertensive rats were given a daily dosage of pure allicin added to their food for six weeks, as compared to control rats that received standard food. At baseline and at the conclusion of the trial, measurements of weight, systolic blood pressure (SBP), triglycerides, cholesterol, insulin, and adiponectin were made. Allicin had no impact

on body weight, however it dramatically lowered triglyceride levels and SBP, dropping SBP from 190 mmHg to 168 mmHg (P<0.0001) and 96 mmHg to 71 mmHg (P=0.009), respectively. Plasma levels of adiponectin, insulin, and cholesterol were unaffected by allicin (Elkayam et al., 2013). The purpose of the study was to determine how Allium sativum affected guinea pigs with experimentally induced hyperlipidemia. 25 guinea pigs were fed cholesterol (0.5 g/Kg body weight/day) for this purpose during the course of an initial 4-week period. The findings demonstrated that garlic's aqueous and alcoholic extracts significantly lowered blood triglycerides, LDL cholesterol, VLDL cholesterol, and atherogenic index in hyperlipidemic guinea pigs (P<0.001) compared to the control group. Animals in group II showed a substantial increase in HDL-C (High-Density Lipoprotein), whereas those in groups I and III did not. A comparison of the two extracts revealed that the aqueous garlic extract was a more effective hypolipidemic medication than the alcoholic extract (Choudhary et al., 2013).

Diallyldisulphide (DADS), an unsaturated aliphatic disulphide, is the major sulphur component found in garlic extract and garlic oil and is regarded to be primarily responsible for the health benefits of garlic. In the current study, rats given a high-lipid diet (HLD) were used to test the efficacy and toxicity of garlic extracts. The findings show that garlic aqueous extracts in high cholesterol diet rats cause fatty liver alterations and hypolipidemic effects in plasma. The main sulfur component in garlic, DADS, may be the cause of these hypolipidemic effects. (Murthy, 2014). Researchers found that supplementing with aged garlic extract (AGE) reduced plasma concentrations of total cholesterol and LDL cholesterol in hypercholesterolemic men by 7% and 10%, respectively, compared to subjects receiving a placebo. This was demonstrated in a randomized, double-blind, placebo-controlled intervention study (Yeh and Liu, 2001). Garlic's capacity to lower blood total cholesterol, LDL and LDL oxidation, platelet aggregation, and hypertension has been demonstrated in several in vitro experiments. It has been demonstrated that garlic inhibits lipid synthesis-related enzymes, reduces platelet aggregation, stops lipid peroxidation of damaged erythrocytes and LDL, boosts antioxidant status, and blocks angiotensin-converting enzymes (Rahman and Lowe, 2006). Consuming garlic promotes fat metabolism and lowers blood cholesterol levels. protects blood arteries and the heart by raising levels of "good" cholesterol HDL and lowering levels of "bad" LDL cholesterol and triglycerides (Majewski, 2014). On the other hand, a little Indian research with 32 hypercholestermic participants combined fish oil use with garlic consumption. With the exception of high-density lipoprotein, which rose, all lipid indicators showed a substantial decrease for the test group. After taking supplements for 60 days, blood triglycerides, very low-density lipoprotein, total cholesterol, and low-density lipoprotein all decreased by 20%, 21%, 37%, 36.7%, and 23.4%, respectively. High-density lipoproteins that are protective went increased by 5.1%. When taken with other antioxidants like lycopene and vitamin E, the potential of garlic may be increased (Bongiorno et al., 2008). When compared to the control group, those who consumed garlic had significantly lower triglyceride (TG) and total cholesterol (TC), the two primary risk factors for arteriosclerosis. When compared to the control group, the administration of 1000 mg of garlic reduces low density lipoprotein cholesterol (LDL-C (Low-Density Lipoprotein)) levels while increasing high density lipoprotein cholesterol (HDL-C (High-Density Lipoprotein)) levels and very low density lipoprotein cholesterol (VLDL-C (Low-Density Lipoprotein)). Therefore, it may be said that garlic may be quite helpful in treating patients who have dyslipidemia (Hussien, 2014). (Brüll et al.,2015) Effects of an onion skin extract high in quercetin on endothelial function and 24-hour ambulatory blood pressure in individuals with (pre-) hypertension who are overweight to obese. Additionally, the World Health Organization endorses the use of onions to cure and prevent atherosclerosis and appetite loss. Similar to garlic, regular onion consumption decreases blood pressure, serum triglyceride and cholesterol levels, while raising HDL levels. As a result, it lowers the risk of heart attacks and strokes and avoids atherosclerosis and diabetic heart disease (Kumar et al., 2010). (Lee et al., 2008) In their investigation on the impact of dietary supplementation with onion powder on lipid metabolism in high fat-cholesterol fed SD In hyperlipidemic rats, it was shown that feeding them onion powder prevented weight growth, markedly reduced the amount of total cholesterol in the liver, and restored GOT function. In rats with Triton X-100-induced hyperlipidemia, ethanolic extracts of Syzygium cumini at doses of 200 and 400 mg/kg significantly reduced hyperlipidemia. Because this component may lower total cholesterol and total triglyceride levels in rats, it was discovered that flavonoids, triterpenoids, and tannins are the active plant elements that were responsible for the anti-hyperlipidemic effect (Singh et al., 2018). After using S. cumini seed powder for 60 days, dyslipidemia has improved (Sidana et al., 2016). In chronic restraint stress mice, the injection of an ethanol extract of S. cumini (L.) pulp considerably reduced the rise in blood pressure (P<0.001). Additionally, the treatment groups' MDA levels were considerably lower than those of the negative controls (P<0.05), showing that an ethanol extract from S. cumini (L.) pulp may stop the rise in MDA levels (Suryajayanti et al., 2017). Diet high in cholesterol Rats showed a statistically significant rise in serum triglycerides, low density lipoproteins, very low density lipoproteins, and the atherogenic index, as well as a statistically significant drop in the ratio of high density lipoproteins to low density lipoproteins (Modi Dikshit et al., 2009). A standardized extract for hypocholesterolemic activity was developed from the leaves of Mangifera indica as a result of a study on the Cholesterol esterase inhibitory activity of bioactives from Mangifera indica L. leaves. The study discovered that the methanolic extract of Mangifera indica leaf had significant anticholesteremic activity (Gururaja et al., 2015). Another study on the impact of ethanol leaf extract of Mangifera indica on the lipid profile of alloxan-induced diabetic albino rats revealed the plant's leaf extract has anti-hyperlipidemic properties, pointing to its potential for treating hyperlipidemia and its associated cardiovascular complications (Ezeani et al., 2017).

Mangifera indica Leaves extract had considerable antihyperlipidemic activity as well as renoprotective and hepatoprotective effects in diabetic albino rats, according

to the study on Assessment of The Therapeutic Role of Mangifera indica Leaves Extract in Diabetic Albino Rats. (Maghfur et al., 2022).

Natural treatments for hyperlipidemia: According to a review, the extract from Mangifera indica leaves acts to increase the expression of hepatic LDL receptors, protect against LDL-C (Low-Density Lipoprotein) buildup in the blood, and catabolize cholesterol from the body's LDL receptors (Dasgupta et al., 2021).

(Arulmozhi et al., 2007) discovered that Myristica fragrans extract effectively decreased the raised TG (47% reduction at 450 mg, $P<0.01$) and cholesterol (66.7% reduction at 450 mg, $P<0.01$) in rats fed a high-cholesterol diet. The extract also demonstrated a reduction in hepatic TG production following tyloxapol treatment. (Vangoori, Y et al., 2019) observed that the concentrations of TC, TD, LDL, and VLDL were substantially ($P<0.05$) and dosage dependently lowered by the ethanolic extract of Myristica fragrans, whereas the concentrations of HDL were raised.

(Kareem et al., 2009) in their study indicated small reductions in the levels of cholesterol (11.0%), triglycerides (21.7%), FFA (53.7%), and PL (10.6%) were seen in rats pretreated with nutmeg extract and then administered isoproterenol. These values were kept at or close to normal by nutmeg extract pretreatment and were 1.86%, 5.54%, 5.65%, and 0.30% for cholesterol, triglycerides, FA, and PL, respectively. (Pashapoor et al., 2020) discovered that giving nutmeg extract to diabetic rats (100 and 200 mg/kg) significantly decreased their levels of malondialdehyde, total cholesterol, triglycerides, and low-density lipoprotein while significantly increasing their levels of high-density lipoprotein cholesterol and total antioxidant capacity. (Sompong et al., 2016), demonstrated that *Syzygium aromaticum* significantly suppressed pancreatic cholesterol esterase activity 1.07% at a dosage of 1 mg/mL. Additionally, they discovered that Syzygium aromaticum had values ranging from 2.29 to 33.74% that marginally inhibited the development of cholesterol micellization. (Nethrakere et al 2015) discovered that as compared to the dexamethasone control group, the clove oil treated groups had significantly lower total cholesterol and triglyceride levels and higher HDL levels ($P<0.01$). The values of HDL, total cholesterol, and triglycerides in the pioglitazone group and the clove oil group, respectively, were comparable ($P = 0.167$, $P = 0.159$, and $P = 0.278$).

Maraia (2014), discovered that clove oil-both fixed and volatile-reduced blood lipid parameters and MDA level, and that this impact was linked to an increase in antioxidant enzyme levels and HDL level.

Previous studies on the benefits of garlic alone have mostly focused on lipid levels. One key difference between our study and several other investigations was the use of garlic in combination with other healthful plants. Only 20 g of garlic and 1 tablespoon of lemon juice were prescribed to the patients, however the aforementioned elements had some noticeable effects. Dry extracts of onion (Allium cepa), black plum (Syzygium cumini), mango (Mangifera indica), nutmeg (Myristica fragrans) fruit, and clove (Syzygium aromaticum) flower were given to research participants, but no particular diet was suggested. When assessing the study's findings, this constraint must be considered. Dietary history for the patient was reviewed.

Conclusions

In conclusion, those with hyperlipidemia have lower lipid levels after taking a combination of dry extracts from the following plants: garlic (Allium sativum), onion (Allium cepa), black plum (Syzygium cumini), mango (Mangifera indica), nutmeg (Myristica fragrans), and clove (Syzygium aromaticum). To determine the appropriate diet and nutritional state of patients, more study is required. Additionally, depending on the degree of the hyperlipidemia, the effects of a combination of dry extracts from the following plants were studied: clove (Syzygium aromaticum) flower, black plum (Syzygium cumini) seed, mango (Mangifera indica) leaf, nutmeg (Myristica fragrans) fruit, and garlic (Allium sativum) dry extract. Accordingly, research is needed to ascertain the effects of dry extracts of the following plants on hyperlipidemia: dried clove flower (Syzygium aromaticum), dried black plum seed (Syzygium cumini), dried mango leaf (Mangifera indica), dried nutmeg fruit (Myristica fragrans), and dried onion (Allium sativum).

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